

K964468

11.5 510(k) Summary

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Name of the Device:

Proprietary name:	lamin® Wet Dressing (Copper-Saline)
Common name:	Hydrogel Dressing
Classification name:	Hydrogel and Burn Dressing

Identification of Predicate Devices to which Substantial Equivalence is Being Claimed:

lamin® Wet Dressing (Copper-Saline) is substantially equivalent in function and intended use to the following non-classified commercially available non-interactive wound and burn dressings:

Dermagran Wet Dressing (Zinc-Saline)
MPM Wet Dressings (Saline)
lamin Hydrating Gel
CarraGauze Hydrogel Wound Dressing

Device Description:

Explanation of how the device functions: lamin® Wet Dressing (Copper-Saline) acts to provide a moist wound environment and protect the wound.

Basic scientific concepts that form the basis for the device: lamin® Wet Dressing (Copper-Saline) was designed to provide a soothing, moist environment for each application to various types of wounds as saturated gauze dressing.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: lamin® Wet Dressing (Copper-Saline) is sterile saturated cotton-blend non-woven gauze.

Statement of the Intended Use of the Device, Including General Description of the Conditions the Device Will Mitigate and the Patient Population for which the Device Is Intended: A hydrogel for the dressing and management of both graft recipient and donor sites, postoperative incisions, pressure ulcers, diabetic ulcers, stasis ulcers, 1st and 2nd degree burns, arterial ulcers, pressure sores, and skin conditions associated with peristomal care. The dressing is intended to cover a wound or burn on a patient's skin, provide a moist wound environment, absorb wound exudate, and protect against abrasion, friction, desiccation, and contamination.

These indication statements are not different from the predicate devices identified above.

Statement of how the Technological Characteristics of the Device Compare to those of the Predicate Device: The technological characteristics of the device such as form, absorptive ability, occlusion, conformability, sterility, moist wound healing and appearance are not different from the predicate devices cited.

Assessment of Performance Data: Biocompatibility testing has been performed as recommended in the "Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing." These tests support the safe use of lamin® Wet Dressing (Copper-Saline) as a temporary dressing in contact with breached or compromised skin.